Avenue Therapeutics Announces Dosing of First Patient in Second Pivotal Phase 3 Clinical Trial of Intravenous Tramadol for the Management of Postoperative Pain

Topline data readout expected in mid-2019

New York, NY – December 19, 2018 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) tramadol, today announced that the first patient has been dosed in a pivotal Phase 3 clinical trial of IV tramadol for the management of moderate to moderately severe pain in patients following abdominoplasty surgery.

"The commencement of the Phase 3 abdominoplasty study is a key step in the advancement of the clinical development for IV tramadol. This study not only compares the efficacy and safety of IV tramadol to placebo, but also compares the safety and tolerability of IV tramadol to an active comparator (IV morphine)," said Lucy Lu, M.D., Avenue's President and Chief Executive Officer. "This is an important aspect of the study, because IV tramadol, if approved, will be used in the hospital setting where IV opioids are already being used and it may be a better alternative for many patients."

The Phase 3, multicenter, randomized, double-blind, three-arm trial will evaluate the efficacy and safety of IV tramadol 50 mg versus placebo. Approximately 360 patients will be enrolled to IV tramadol 50 mg, placebo or morphine in a 3:3:2 ratio. The primary efficacy endpoint is the summed pain intensity difference over 24 hours (SPID24) compared to placebo. Additional information on the study can be found on www.clinicaltrials.gov using the identifier NCT03774836.

About Avenue Therapeutics
Avenue, a Fortress Biotech company, is a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) tramadol for the management of moderate to moderately severe postoperative pain. IV tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAIDs and IV conventional narcotics. Avenue is currently evaluating IV tramadol in a pivotal Phase 3 program for the management of postoperative pain. Avenue is headquartered in New York City. For more information, visit www.avenuetx.com.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress") (NASDAQ: FBIO) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements
This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our

growth strategy; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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